ARC 0769D

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Rulemaking related to certificate of need

The Department of Health and Human Services hereby amends Chapter 123, "Certificate of Need Program," and Chapter 124, "Standards for Certificate of Need Review," Iowa Administrative Code.

Legal Authority for Rulemaking

This rulemaking is adopted under the authority provided in Iowa Code section 135.71.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, Iowa Code section 135.71 and 2026 Iowa Acts, House File 2635.

Purpose and Summary

The purpose of this rulemaking is to implement the provisions of 2026 Iowa Acts, House File 2635, which changes the requirements for obtaining a certificate of need by, among other things:

- Eliminating the requirement to submit a letter of intent;
- Eliminating the requirement for a public hearing; and
- Excluding the following from the certificate of need requirement:
  - Cardiac catheterization service;
  - Open heart surgical service;
  - Organ transplantation service; and
  - Some radiation therapy services for the treatment of malignant disease.

Public Comment and Changes to Rulemaking

Notice of Intended Action for this rulemaking was published in the Iowa Administrative Bulletin on September 30, 2026, as **ARC 0618D**. A public hearing was held on the following date(s):

- October 20, 2026

No one attended the public hearing. No public comments were received.

One change from the Notice has been made. In subrule 123.3(1), the word "renewability" should have been "reviewability." That correction has been made.

Adoption of Rulemaking

This rulemaking was adopted by the Department on November 4, 2026.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rulemaking, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 441—Chapter 2504.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rulemaking will become effective on January 1, 2027.

The following rulemaking action is adopted:

ITEM 1. Amend rule 441—123.1(135) as follows:

441—123.1(135) ~~Definitions~~ Definition. For purposes of this chapter, the following ~~definitions apply~~ definition applies:

"Long-term (acute) care hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a long-term care hospital-prospective payment system (LTCH-PPS) hospital in accordance with 42 CFR Part 412 as amended to August 1, 2025.

~~*"Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment,"* as the term applies to new or changed institutional health service in Iowa Code section 135.61(17)*"m"*(4), means the initiation or expansion of this service.~~

ITEM 2. Rescind rule **441—123.2(135)**.

ITEM 3. Renumber rules **441—123.3(135)** to **441—123.12(135)** as **441—123.2(135)** to **441—123.11(135)**.

ITEM 4. Amend renumbered rule 441—123.2(135) as follows:

441—123.2(135) Determination of reviewability. A sponsor of a proposed project may electronically submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

123.2(1) If it is determined that a certificate of need is required, the department will notify the sponsor ~~and the request for nonreviewability will be considered the letter of intent for purposes of subrule 123.2(2)~~ of the determination of reviewability and the sponsor will be allowed to submit an electronic application immediately.

123.2(2) If it is determined that a certificate of need is not required, the department will notify the sponsor of the determination of nonreviewability.

ITEM 5. Amend renumbered rule 441—123.3(135) as follows:

441—123.3(135) Submission of application.

123.3(1) Application form.

a. A sponsor of a proposed project for a new or changed institutional health service will submit to the department an electronic application for certificate of need using the appropriate application form found on the certificate of need website. All information requested in the application form is required in the absence of a waiver by the department.

b. and *c.* No change.

123.3(2) No change.

123.3(3) The notice of an accepted application issued pursuant to Iowa Code section 135.65(2) will inform the applicant and affected persons of the deadlines for the electronic submission to the department of written ~~statements~~ public comments or other materials.

ITEM 6. Amend renumbered subrule 123.4(2) as follows:

123.4(2) Public comments on an application.

a. The department will receive written public comments on an application during a time frame prescribed by the department for each application. ~~Oral comments will be received at a public hearing set by the department.~~

b. No change.

ITEM 7. Amend renumbered subrules 123.5(1) to 123.5(3) as follows:

123.5(1) An applicant will electronically submit a written request for summary review and a copy of the application and all attachments. ~~An applicant is not required to submit a letter of intent pursuant to Iowa Code section 135.64 prior to submitting a written request for a summary review.~~

123.5(2) The eligibility of an application for summary review pursuant to Iowa Code section 135.66 ~~does not mandate or require such review. The department will make the decision as to whether an application will be reviewed in the summary review process~~ will be at the department's discretion.

123.5(3) Upon receipt of a ~~written~~ request for summary review, an application, and the fee required by Iowa Code section 135.62(1), the department will notify the applicant ~~in writing~~ within 15 calendar days if the application is complete and if a summary review will be granted.

ITEM 8. Amend renumbered subrule 123.6(2) as follows:

123.6(2) An extension by the department made pursuant to subrule ~~123.7(1)~~ 123.6(1) will in no case be more than ~~60~~ 30 calendar days beyond the time a decision is required under Iowa Code section 135.68 unless the applicant and the department agree.

ITEM 9. Amend renumbered subrule 123.7(1) as follows:

123.7(1) An applicant or any affected person who has participated or sought unsuccessfully to participate in the formal review procedure prescribed in Iowa Code section 135.65 may, for good cause shown, electronically file an application for rehearing ~~in writing~~ with the department stating the specific grounds therefor and the relief sought within 20 calendar days after the date of the issuance of the final decision on an application for certificate of need.

ITEM 10. Amend renumbered rule 441—123.8(135) as follows:

441—123.8(135) Finality. The certificate of need application process is continuous beginning with submission of ~~a letter of intent or request for waiver of a letter of intent~~ an application through issuance of a final decision by the department subject to judicial review under Iowa Code chapter 17A.

123.8(1) The following stages of the process are intermediate and subject to judicial review only to the extent the stages meet criteria for intermediate review under Iowa Code section 17A.19:

a. A decision by the department pursuant to rule ~~441—123.3(135)~~ 441—123.2(135) that a proposed project does not require a certificate of need;

b. A decision by the department to ~~waive submission of the letter of intent and substitute~~ conduct summary review; and

c. No change.

123.8(2) No change.

ITEM 11. Amend renumbered subrule 123.10(1) as follows:

123.10(1) Once a project has been approved by the department, no changes that vary from or alter the number of approved beds, the approved services or the approved cost by an amount indicated in subrule ~~123.11(2)~~ 123.10(2) may be made unless requested by the applicant and approved by the department. Requests should be ~~made in writing and~~ filed with the department electronically.

ITEM 12. Rescind rule **441—124.1(135)**.

ITEM 13. Rescind rule **441—124.2(135)**.

ITEM 14. Renumber rules **441—124.3(135)** to **441—124.6(135)** as **441—124.1(135)** to **441—124.4(135)**.

ITEM 15. Amend renumbered subrule 124.1(2) as follows:

124.1(2) *Definitions.* The following definitions apply to the terms used in this rule:

~~*"Active oncology service"* means full, multidisciplinary cancer care, provided by a medical team that would include: surgery, gynecology, medical oncology, radiation oncology, pathology, diagnostic radiology and nuclear medicine. The surgery specialties that might be available would include: thoracic, abdominal, genitourinary and gynecological. The active oncology staff would include those specialists with training in oncology, hematology, and pathology and who spend at least half of their time at the institution.~~

"Applicant" means a facility or a consortium of facilities within an area or a physician or group of physicians.

~~*"Chemotherapy service"* means the treatment of cancer by chemical agents.~~

"Computerized tomographic (CT) scanner" means a diagnostic tool that rotates around the body and that sends X-ray beams through the body or brain. The X-ray beams that emerge from the body or brain are absorbed by a detector. Differences in the amount of X-rays absorbed by the detector indicate differences in tissue density. As the scanner rotates, it takes many images of a volume or cross-section. The images on the detector are transmitted to a computer that displays on a monitor a reconstructed cross-sectional slice or volume. Contrast media is often injected to alter absorption of the detector. If the scan is repeated, it is called enhancement. Studies of the heart, arteries and veins may be done with contrast only.

"CT consortia" means a cooperative venture in which two or more institutions form a separate entity that is created for the purpose of owning, leasing, planning for, and maintaining the use of the scanner. Each facility in the consortium maintains its autonomy for all other services.

"Emergency medical service (EMS) level II trauma service" means the level of various services and staffing that qualify a facility to be designated by the department, using the facilities categorization criteria of such services that is in effect on the date of the enactment of this standard.

"Enhanced scan" means a scan performed on a patient who has been administered a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

"General imaging procedures" means a radiological diagnostic procedure performed on an X-ray machine or similar radiological diagnostic instrument.

"Head scanner" means a scanner capable of imaging only the brain and structures adjacent to the head.

"Minimum shared-market area for a scanner" (hereafter referred to as "area") means the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner in the community (as defined by the U.S. Bureau of the Census) or a standard metropolitan statistical area (where an area is so designated).

"Radiotherapy service" means the therapeutic application of megavoltage radiation, using a linear accelerator or cobalt unit. The availability of such service at a hospital would necessitate personnel trained in the therapeutic application of radiology.

"Shared service agreement" means a multi-institutional arrangement for coordination or consolidation of services or sharing of support services. Among the various types of arrangements are referred services, purchased or joint contract services, multisponsored services and regional services.

"Whole body scanner" means a scanner capable of imaging the entire body.

ITEM 16. Amend renumbered subparagraph **124.1(3)"a"(2)** as follows:

(2) An applicant in an area with one or more scanners.

1. An applicant must meet the requirement of need described in subparagraph ~~124.4(3)~~ 124.2(3) *"a"*(1), and

2. No change.

3. University of Iowa Health Care is specifically exempted from consideration under numbered paragraph ~~124.3(3)~~ 124.3(2)*"a"*(2)"2" because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for scanners at the University of Nebraska Medical Center and Creighton University Medical Center – Bergan Mercy (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

ITEM 17. Amend renumbered subparagraph **124.3(3)"b"(1)** as follows:

(1) An applicant must meet the requirement of need described in paragraph ~~124.5(3)~~ 124.3(3)*"a,"* and

ITEM 18. Amend renumbered subrule 124.4(3) as follows:

124.4(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"h"*)

a. No change.

b. An applicant in an area with one or more PET units currently in operation or approved by the certificate of need program for operation.

Existing PET units within the area (whether basic or enhanced) should have been operating at a minimum of 1,000 PET procedures during the most recent annual period as reported to the certificate of need program according to paragraph ~~124.6(4)~~ 124.4(4)*"e."*

[Filed 11/4/26, effective 1/1/27]
[Published 11/25/26]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 11/25/26.